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August 18, 2020

Via ECF Filing

The Honorable Maryellen Noreika
United States District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *Biogen Int'l GmbH. et al. v. Cipla Limited et al.*
C.A. No. 17-cv-00851-MN (Consolidated)
(lead case: 17-cv-00823-MN)

Dear Judge Noreika:

We represent Defendants Cipla Limited and Cipla USA Inc. in connection with *Biogen International GMBH and Biogen MA Inc. v. Amneal Pharmaceuticals LLC et al.*, 1:17-cv-0823-LPS (consolidated) and 1:17-cv-00851-LPS. We write to update the Court of recent developments since the August 11, 2020 hearing on collateral estoppel.

During the hearing, counsel for Biogen indicated that Mylan would likely not receive FDA approval until November or December of this year. However, yesterday the FDA approved Mylan's generic product. See Exhibit A attached hereto (Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Product Details for ANDA 210531, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=210531# (last accessed Aug. 18, 2020)).

Mylan's FDA approval, coupled with the invalidity decision in its district court litigation, allows Mylan to commercialize its generic dimethyl fumarate

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product immediately. This commercially prejudices all of the defendants in the Delaware action, who cannot receive final approval until this Court enters a final decision or the 30-month stay expires.

In view of these recent developments and their prejudicial impact on the defendants in this case, Cipla respectfully requests that the Court issue its ruling with respect to the collateral estoppel issue as soon as possible.

Respectfully submitted,

/s/ Daniel B. Rath

Daniel B. Rath

DBR/mr

cc: All counsel of record (via electronic mail)